

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

PATRICIA MUNION and
DAVID MUNION
Plaintiffs,

vs.

ADVANCED MEDICAL OPTICS

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CIVIL ACTION NO. 07-5377

JUDGE JOSEPH H. RODRIGUEZ

JURY TRIAL DEMANDED

**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF
SECOND MOTION FOR LEAVE TO AMEND COMPLAINT
TO NAME AN ADDITIONAL DEFENDANT**

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Plaintiffs Patricia and David Munion, by undersigned counsel, respectfully submit this reply memorandum in further support of their motion for leave to file an amended complaint to add an additional defendant Allergan, Inc. ("Allergan"), which motion is scheduled for argument on February 6, 2009.

Preliminary Statement

Defendant Advanced Medical Optics ("AMO") filed a brief in opposition to plaintiff motion for leave to join an additional defendant Allergan, Inc. ("Allergan") which is essentially a premature motion to dismiss the proposed amended complaint. It is undisputed that Allergan, the predecessor to AMO, was involved in the design of and selection of ingredients in the contact lens solution which came to be marketed as COMPLETE® MoisturePlus™ Multi-Purpose Solution ("COMPLETE Moisture Plus"). Indeed, Allergan continued to manufacture the product until 2005. It is also undisputed that Allergan is a named defendant in the consolidated group of over 60 cases pending in California state court and has produced approximately 100,000 pages of documents in discovery in those cases. In fact, AMO and Allergan are represented by the same counsel in the California cases.

Mrs. Munion sustained permanent loss of sight and other injuries in her right eye, as a result of her use of COMPLETE Moisture Plus, a contact lens solution manufactured by AMO and designed by Allergan. Clearly, Allergan can be properly joined as a party defendant in this case. AMO seeks to prevent the joinder of Allergan

in this case, simply as part of its strategy to delay discovery and escalate the costs of litigation for the plaintiffs. AMO is trying to prevent the production of the same Allergan documents in this case, that AMO - Allergan counsel must produce pursuant to court orders in California. In fact, Allergan as a result of the strategy of AMO's counsel has been sanctioned over \$25,000 for dilatory production and discovery violations in California.

I. LEGAL ARGUMENT

A. Plaintiffs' Proposed Amendments Are Not Futile.

The Federal Rules of Civil Procedure provide a liberal standard for the amendment of pleadings to ensure that claims will be decided on the merits rather than on technicalities or case management concerns. Alvin v. Suzuki, 227 F.3d 107, 121-123 (3d Cir. 2000). An amendment is futile only if the amended complaint cannot survive a motion to dismiss for failure to state a claim upon which relief could be granted. *Id.* at 121. To determine whether an amendment is futile, the court must apply the same standard of legal sufficiency as applicable under Rule 12(b)(6). Thomason v. Potter, 2008 U.S. Dist LEXIS 80495 at *5-6 (D.N.J. 2008) (*quoting In re Burlington Coat Factory Sec.Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997)). This standard of review "requires the court to accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party." *Id.* at *5-6 (*quoting Rocks v. City of Philadelphia*, 868 F.2d 644, 645 (3d Cir. 1989)).

The defendant's burden of demonstrating the futility of an amendment is not met

by conclusory contentions untested by the discovery process. As explained in Aruanno v. State of New Jersey, 2009 U.S. Dist. LEXIS 2744, at *6 (D.N.J. 2009), “courts place a heavy burden on opponents who wish to declare a proposed amendment futile. Thus, the proposed amendment must be frivolous or advance a claim that is insufficient on its face.”

Contrary to AMO’s contentions, plaintiff’s proposed amendments are not futile. In summary, Allergan participated in the design and formulation of the contact lens solution at issue and clearly falls within the definition of a “manufacturer” under the New Jersey Product Liability Law (“NJPLA”). N.J.S.A. §§2A:58C-2. Additionally, AMO itself recognized the viability of plaintiffs’ breach of express warranty claim by answering this count when it was asserted in the original Complaint, without asserting any basis for dismissal by motion. Moreover, plaintiff David Munion clearly has a claim for loss of consortium, which is a defined “harm” under the NJPLA. N.J.S.A. §§2A:58C-1.b.(2).

The causes of action for common law fraud and negligent misrepresentation alleged in the proposed Amended Complaint are limited to the fraudulent and deceptive promotion marketing and advertising campaign of the defendants and their intentional concealment of material facts regarding the risk of using COMPLETE Moisture Plus. See, Knipe v. Smithkline Beecham, 583 F. Supp. 2d 602, 2008 U.S. Dist. LEXIS 76774, *37-39 (E.D. Pa. Sep. 30, 2008) (recognizing under New Jersey Law an exception to the general principal of subsumption where harm is alleged to come not from use of the product but instead from the fraud or deception of the defendants). Finally, the claim for punitive damages remains viable as to the contact lens product in this case, which is distinguishable from prescription drugs.

B. Allergan is a Product “Manufacturer” as defined under the New Jersey Product Liability Act.

Plaintiffs seek to assert claims against Allergan under the New Jersey Product Liability Act (“NJPLA”).¹ The NJPLA at §2A:58C-8 defines a product “manufacturer” in pertinent part as follows:

“Manufacturer” means (1) **any person who designs, formulates, produces, creates, makes, packages, labels or constructs any product or component of a product**; (2) a product seller with respect to a given product to the extent the product seller designs, formulates, produces, creates, makes, packages, labels or constructs the product before it sale.

(emphasis added). The NJPLA at §2A:58C-8 separately defines a product “seller.”

Reading these two definitions, “manufacturer” and “product seller” together, it is clear that **“any person”** who designs, formulates or selects the ingredients for the contact lens solution product at issue in this litigation is within the ambit of liability imposed under the NJPLA. Defendant AMO’s public policy argument directly conflicts with the clear wording of the NJPLA and the legislative intent.

None of the cases cited in defendant’s brief support AMO’s contention that a company like Allergan, which designed the formula of the contact lens solution product is not a manufacturer under the NJPLA. In Becker v. Tessitore, 356 N.J. Super 233,

¹ N.J.S.A. §2A:58C-2 provides for the liability of a manufacturer or seller in a product liability action as follows:

A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae or performance standards of the manufacturer . . . or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

254 (App. Div. 2002), the plaintiff was involved in an accident when he was struck by a piece of blown tire retread which split from a tire on a truck owned and operated by the defendant trucking company. The plaintiff attempted to bring a strict liability claim under the NJPLA against the trucking company, which had purchased retreading for the tire from a retread supplier so that the tire could be used by the trucking company on its own trucks. The trucking company had never produced or sold its own tires to the public. The Appellate Court held that the trucking company fell outside the statutory definition of a manufacturer because (1) the trucking company never held itself out as a tire manufacturer; and (2) the trucking company "did not design, formulate, produce, create, make, package or construct the retread. " These facts are totally different than the situation concerning Allergan, which not only engaged in the business of manufacturing contact lens solutions but also is alleged to have designed the formula for the lens solution which permanently injured Mrs. Munion.

Similarly, in Ramos v. Silent Hoist & Crane Co., 256 N.J. Super. 467, 475-477 (App. Div. 1992), the Court was not faced with the "designer" of the product at issue. The plaintiff in Ramos was injured when he became entangled in a capstan after turning on the electrical power to help a ship dock when the regular docking crew was absent. The capstan did not have a control or emergency off switch on the product itself. The plaintiff attempted to assert a strict liability claim against the electric company which ran and installed the electric power lines to the capstan. The Appellate Court held that the installation of the electrical system did not involve the sale of a product. Additionally, the installation of electric power did not involve the provision of a defective component part of the capstan simply because the electrician installed the

power to the product, thereby, enabling the capstan to run. Instead, the liability of the electrician-installer was to be determined under negligence principles not strict liability. In sharp contrast to the Ramos case, Allergan is the “designer” of the contact lens solution which injured plaintiff in this case.

AMO argues that because AMO remains a viable defendant manufacturer, all predecessors in the COMPLETE Moisture Plus product line who may have designed the product are relieved of liability. The argument that a predecessor is entitled to judgment as a matter of law as long as the company’s successor is still susceptible to suit was specifically rejected by the New Jersey Supreme Court in Nieves v. Bruno Sherman Corp., 86 N.J. 361, 365 (1981). Nieves held that the product line rationale applicable in strict liability cases “is not so limited as to visit liability upon only the current, viable manufacturer of the product line.” To the contrary, both the current successor corporation and its predecessors may be responsible. Id. at 365.² Even if AMO may have assumed responsibility by means of an indemnification agreement or other arrangement when Allergan allegedly spun off AMO in 2002, that does not result

² AMO’s reliance upon Potwora v. Grip, 319 N.J. Super 386 (App. Div.), *cert denied*, 161 N.J. 151 (1999), for the proposition that a predecessor company in the product line should not be liable where a viable defendant in the product line is in existence is misplaced. First, It should be noted that the plaintiff in Potwora was seeking to hold the successor to a predecessor defendant which did not design the “helmet” at issue in the accident. Instead, the predecessor had designed a similar helmet, and plaintiff was trying to hold a successor of the predecessor responsible for the design of a “similar helmet” as a “de facto designer.” The facts in Potwora are readily distinguishable from Allergan’s role in this case, as the designer of the lens solution which continued to manufacture the Complete Moisture Plus product for several years after it allegedly spun off the AMO division.

in the conclusion at the pleading stage that Allergan is not a “manufacturer” within the meaning of the NJPLA. Indeed, Allergan has admitted in discovery answers that it continued to make the COMPLETE Moisture Plus product until 2005.

What is AMO really trying to accomplish by blocking the joinder of Allergan as a defendant in this case? The answer is simple. AMO seeks to preclude the addition of Allergan as a party defendant in this case in order to escalate the costs of discovery and prevent plaintiffs from obtaining discovery and particularly damaging documents from Allergan. AMO’s motion should be denied with respect to each and every claim asserted by either plaintiff under the NJPLA.

C. Whether or Not Plaintiffs Can Establish Causation to Allergan is Premature at the Motion to Amend Stage.

AMO seeks to circumvent joinder of Allergan contending that plaintiffs cannot establish causation for the injuries sustained as a result of use of the contact lens solution allegedly designed by Allergan. Defendants are essentially making an argument that is only appropriate at the summary judgment stage. The clear terms of the NJPLA provide that a “manufacturer” of a product shall be liable in a product liability action if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable, or safe for its intended purpose because it “was designed in a defective manner.” N.J.S.A. §2A:58C-2. Therefore, the jury question essential to this inquiry is whether Allergan’s defective design of the formulation of the COMPLETE Moisture Plus product was a proximate cause of the plaintiff’s injury, that is, a substantial contributing factor to the harm sustained by plaintiff. McDarby v. Merck, 401 N.J. Super 10, 84-86 (App. Div. 2008). Clearly, that

question cannot be determined at the pleading stage without discovery.

D. Count IV of the Proposed Amended Complaint states a Cause of Action for Breach of Express Warranty.

Express warranties are governed by the UCC, embodied in N.J.S.A. § 12A:2-313(1), which provides that express warranties are created by any "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain" or "description of the goods which is made part of the basis of the bargain." Viking Yacht Co. v. Composites One LLC, 496 F. Supp. 2d 462, 469 (D. N.J. 2007). To recover for breach of express warranty, a plaintiff must show that a warranty exists and that there was a breach of that warranty. Cipollone v. Liggett Group, Inc., 893 F.2d 541, 575 n.42 (3d Cir. 1990). Proof of a breach does not require the plaintiff to prove privity or traditional reliance. Knipe v. Smithkline Beecham, 583 F. Supp. 2d 602, 2008 U.S. Dist. LEXIS 76774, at *58 (E.D. Pa. 2008) (applying New Jersey law).

Count IV of the proposed Amended Complaint sets forth each of the essential elements for a breach of warranty claim and puts the defendants on notice of the basis for the claim. It is noteworthy, that AMO originally answered plaintiff's breach of warranty claim in the original complaint. AMO engaged in a widespread promotional campaign which included express representations as to the safety and efficacy of COMPLETE Moisture Plus for the cleaning, disinfection and storage of soft contact lenses. The promotional literature of defendants, including the packaging of the product made warranties that the product was safe, effective and proper for contact lens cleaning and storage. Yet at the same time, COMPLETE Moisture Plus, as

defendants knew, did not conform to these representations, and was ineffective as a disinfective against harmful micro-organisms, including *Acanthamoeba*. Moreover, by design, and as a result of the ingredients in the formula, COMPLETE Moisture Plus was more conducive to development of AK than other contact lens solutions on the market. Plaintiff alleges that the solution did not clean, or destroy micro-organisms on the surface of the lenses used by plaintiff. To the contrary, plaintiff suffered severe and sight-threatening injury caused by a parasite, which the solution admittedly did not kill. Plaintiff developed AK, lost the sight in her right eye and the pupil of her right eye is permanently dilated and cannot be corrected.

Defendants added several so-called comfort ingredients to COMPLETE Moisture Plus, including the lubricant propylene glycol (used in anti-freeze and sex lubricants and which was not contained in other lens solutions) and the amino acid taurine. These new moisturizer ingredients became the focus of a marketing campaign ("REJUVENATE with Tear-Like Moisturizers and Electrolytes"). The promotional literature touted the safety and efficacy of COMPLETE Moisture Plus solution proclaiming that its key lubrication ingredient, propylene glycol, "penetrates and keeps water inside the lens" and works to "rejuvenate with . . . tear like moisturizers."

Yet, in a recent study conducted by Dr. Simon Kilvington, a UK *acanthamoeba* specialist and current employee of AMO, in conjunction with several other AMO employees, identified the propylene glycol ingredient as one of the contributors to the AK outbreak among users of COMPLETE Moisture Plus. Propylene glycol is not an ingredient found in most other contact lens solutions. The study investigated the physiologic response of *Acanthamoeba* trophozoites to incubation in various contact

lens solutions. The *Acanthamoeba* trophozoites were incubated in commercial solutions and the percentage encystment (dormant stage) and viability determined in conjunction with cyst formation. The study concluded that "The presence of propylene glycol was shown to be the key factor found in inducing *Acanthamoeba* encystment." Kilvington et al, "Encystment of *Acanthamoeba* During Incubation in Multipurpose Contact Lens Disinfectant Solutions and Experimental Formulations." Moreover, the study proved that COMPLETE Moisture Plus acts very differently on *acanthamoeba* than any other solution, causing the *acanthamoeba* to encyst (but does not kill it).³ The study also found that the cysts produced from incubation in the COMPLETE Moisture Plus solution *were viable*.

It remains to be seen in discovery whether or not Allergan played any role in the warranties and representations made with respect to the COMPLETE Moisture Plus solution. Count IV of the proposed amended complaint is not futile and the proposed amendments should be permitted.

E. Plaintiff David Munion Has a Claim for Consortium.

Plaintiff David Munion has a valid claim for consortium. In Count VIII of the proposed amended complaint, plaintiff David Munion realleges all of the preceding paragraphs. It is clear that David Munion has a claim for loss of consortium under the

³ "Of the commercial contact lens care solutions tested in this study, Moisture Plus MPS was found to induce *Acanthamoeba* encystment. Further investigation indicated that propylene glycol was the key ingredient responsible for this phenomenon. When modified formulations of Moisture Plus MPS were prepared that lacked particular components, encystment only occurred in those containing propylene glycol." Eye & Contact Lens 34(3): 137 (2008), Kilvington et al, "Encystment of *Acanthamoeba* During Incubation in Multipurpose Contact Lens Disinfectant Solutions and Experimental Formulations."

NJPLA which defines “harm” as including any loss of consortium or services or other loss deriving from any type of physical injury, pain or suffering of his spouse.

NJSA §2A:58C-1b.(2)(d). Therefore, AMO’s objection to the consortium claim in the proposed amended complaint can be mooted by adding the statute cite for the NJPLA in Count VIII.

F. The Proposed Amended Complaint States Viable Causes of Action for Fraud, and Negligent Misrepresentation.

By its terms, under the NJPLA “product liability action” means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim except for actions for harm caused by breach of an express warranty.” N.J.S.A. §§2A:58-C-1B(3); Sinclair v. Merck, 195 N.J. 51, 948 A.2d. 587 (2008). The Sinclair case was an action brought by plaintiffs for medical monitoring as a result of the use of Vioxx, a prescription drug manufactured by Merck. Initially, Merck moved to dismiss the class action complaint for failure to state a claim on the grounds that the NJPLA and its definition of harm did not apply to medical monitoring. The Court held that the NJPLA requires a physical injury and claims for medical monitoring without an alleged physical injury must fail under the NJPLA.

The plaintiff class in Sinclair sought to avoid the requirements of the NJPLA by asserting a claim under the New Jersey Consumer Fraud Act. Finding that the heart of plaintiffs’ case was the potential for harm caused by Merck’s drug, the New Jersey Supreme Court in Sinclair held that any Consumer Fraud Act claims were subsumed into the NJPLA, which was the sole source of remedy for plaintiffs’ product claim.

We recognize that depending on the factual circumstances, New Jersey federal

and state Courts have determined that negligent misrepresentation and fraud claims can be among the claims subsumed by the NJPLA. Therefore, in the instance where plaintiffs assert fraud and misrepresentation claims based on an allegation that the contact lens product was "not reasonably fit for its intended use because of inadequate warnings," such claims are subsumed by the NJPLA. Knipe, 2008 U.S. Dist. LEXIS at *38. However, when a claim is premised on misleading, false or materially deficient advertising, it may not be subsumed under an analysis that it is the fraudulent promotion not the product that caused the harm. *Id.* Plaintiffs' proposed amended complaint avers claims for fraud and negligent misrepresentations arising from and specifically limited to the deceptive sales and marketing campaign of the defendants. This claim is different than the Consumer Fraud Act which precludes consumer claims for non-economic damages such as those arising from personal injuries. Cole v. Laughrey Funeral Home, 376 N.J. Super. 135 (App. Div. 2005).

G. The Count for Punitive Damages Is Not Barred as a Matter of Law.

Contact lens solutions are categorized as Class II medical devices under the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug and Cosmetic Act of 1938. As a result, manufacturers of contact lens solutions are allowed to avoid the costly and strict premarket approval process required for Class III medical devices, by which the FDA approves the safety and efficacy of certain devices. Instead, contact lens solutions are allowed to be marketed through the 510k Clearance Procedure. Under this procedure, the FDA clears - as opposed to approves - new solutions for marketing if the manufacturer shows that the solution is "substantially equivalent" to a solution that is already on the market.

AMO asserts that under the decision of McDarby v. Merck, 401 N.J. Super 10, (App. Div. 2008), any and all claims for punitive damages under the NJPLA are preempted because such claims require a state law determination of a fraud-on-the-FDA claim. However, other claims which arise in connection with misleading, false or materially deficient product advertisements remain viable. Knipe, 2008 U.S. Dist. LEXIS at *102-05 (holding punitive damages claim permissible where fraud on the FDA is not the basis for the claim).

Also, since this case involves a contact lens solution and not a prescription drug or Class III medical device, there is a question of whether the 510(k) clearance for the marketing of COMPLETE Moisture Plus constitutes “premarket approval” or licensure by the FDA under the terms of the NJPLA limitation on punitive damages in N.J.S.A. §2A:58C-5. For purposes of preemption, the United States Supreme Court in Medtronic v. Lohr, 518 U.S. 470, 116 S. Ct. 2240, 135 L.Ed. 2d 700 (1996), distinguished the FDA clearance procedure under Section 510(k) from the more rigorous FDA “premarket approval process”. Under Lohr the clearance procedure does not constitute either an approval by the FDA of the safety of the formula of COMPLETE Moisture Plus nor is it an approval by the FDA of any labeling for the lens solution. Accordingly, plaintiffs’ claims are not preempted under the express preemption provision of the MDA contained in Section 360k(a). Lohr, 518 U.S. 470. This holding was reaffirmed by the Supreme Court in Reigel v. Medtronic, 128 S. Ct. 999, 169 L.Ed 2d 892, 899 (2008), which distinguished the “substantially equivalent” procedure under 510k from the more rigorous premarket approval for new Class III devices. Only the rigorous “premarket approval” which is a “federal safety review” used

for Class III medical devices triggers preemption under the MDA. “[Section] 510(k) is “focused on *equivalence*, not safety”. . . premarket approval is focused on safety not equivalence. . . devices that enter the market through §510(k) have “never been formally reviewed under the MDA for safety or efficacy.” Reigel, 128 S. Ct. at 1007, *quoting Lohr*, 518 U.S. at 493. Applying this analysis employed by the United States Supreme Court to the use of the words “premarket approval” in N.J.S.A. § 2A:58C-5(c), the contact lens solution product at issue here was not subjected to the same stringent approval process reserved for prescription drugs like Vioxx (in McDarby).

Medical devices under the MDA are classified into three categories: Class I which includes devices like elastic bandages and examination gloves subject to the lowest level of oversight with “general controls” such as labeling requirements; Class II which includes devices like powered wheelchairs and surgical drapes which are subject to “special controls” such as performance standards and postmarket surveillance measures and Class III, which is the most stringent classification subject to the greatest level of federal oversight for dealing with devices for a use in supporting or sustaining human life. Reigel, 128 S. Ct. at 1004, 169 L.Ed 2d at 899.

In 1996, the FDA decided to downgrade the classification of contact lenses (and solutions used in connection with contact lenses) from the more stringent Class III to Class II. In connection with the downgrading of the classification of contact lens products to Class II the FDA issued a Guidance for Industry dated May 1, 1997 for the Premarket Notification procedure under Section 510k.⁴

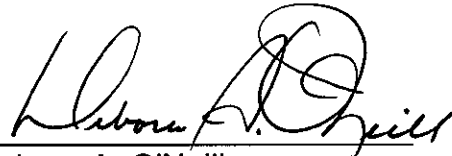
⁴ The Guidance, which sets forth the minimum requirements to meet a substantial equivalence review, contains a disclaimer by the FDA that it was not a

As a result, plaintiff's claims for punitive damages based on defective design are not fraud on the FDA claims and are not preempted under the holding in McDarby. This issue cannot be decided at the pleading stage without the benefit of discovery and the FDA clearance process as applied to the contact lens solution product in this case. The issue of punitive damages is more properly raised at the time for summary judgment and the count should remain in the proposed amended complaint.

II. CONCLUSION

For all of the foregoing reasons, Plaintiffs' Second Motion for Leave to Amend Complaint to Name an Additional Defendant should be granted.

Respectfully submitted,



Dated: January 29, 2009

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statement of FDA requirements stating instead:

This document represents the agency's current thinking on the preparation of a 510(k) for contact lens care products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

CERTIFICATE OF SERVICE

DEBORA A. O'NEILL, ESQ., hereby certifies that service of the foregoing Plaintiffs' Reply Memorandum in Support of Second Motion for Leave to Amend Complaint to Name an Additional Defendant was made upon counsel listed below by regular mail on January 29, 2009:

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A handwritten signature in black ink, appearing to read "Debora A. O'Neill", written over a horizontal line.

Debora A. O'Neill